

K070062

Appendix C

JUL 30 2007

510(k) Summary of Safety and Effectiveness

<i>Name</i>	<i>DIESSE Diagnostica Senese SpA</i>
<i>Address</i>	<i>Via delle Rose 10, 53035 Monteriggioni SI</i> <i>Tel. 39-0577- 587111</i> <i>Fax 39-0577-318690</i>
<i>Contact Person</i>	<i>Dr. Francesco Cocola</i>
<i>Phone Number</i>	<i>39-0577-587143</i>
<i>Fax Number</i>	<i>39-0577-318379</i>

The Following section is included as required by
the Safe Medical Device Act (SMDA) 1990.

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: _____

1 GENERAL INFORMATION

1.1 Applicant

Date	September 19, 2006
Name	DIESSE Diagnostica Senese SpA
Address	Via delle Rose 10, 53035 Monteriggioni SI, Italy Tel. 011-39-0577- 587111 Fax 011-39-0577-318690
Contact Person	Dr. Francesco Cocola
Phone Number	39-0577-587143
Fax Number	39-0577-318379

1.2 Device information

Proprietary Device Name	<i>Coproset Shigella</i>	<i>Coproset Salmonella</i>	<i>Uriset Preservative tube</i>	<i>Swab Set General Use</i>
Device model number	94052	94050	94026	94320
Type of Submission	Third Party	Third Party	Third Party	Third Party
Common Name Or Classification Name	Microbiological specimen collection and transport Device, <i>Coproset</i> (866.2900)	Microbiological specimen collection and transport Device, <i>Coproset</i> (866.2900)	Microbiological specimen collection and transport Device, <i>Uriset</i> (866.2900)	Microbiological specimen collection and transport Device, <i>Swabset general use</i> (866.2900)
Establishment Registration Number	807.87 (b) 9615056	807.87 (b) 9615056	807.87 (b) 9615056	807.87 (b) 9615056
Facility Address	Via delle Rose 10 53035 Monteriggioni SI, Italy Tel.: 39-0577-587111 Fax: 39-0577-318690	Via delle Rose 10 53035 Monteriggioni SI, Italy Tel.: 39-0577-587111 Fax: 39-0577-318690	Via delle Rose 10 53035 Monteriggioni SI, Italy Tel.: 39-0577-587111 Fax: 39-0577-318690	Via delle Rose 10 53035 Monteriggioni SI, Italy Tel.: 39-0577-587111 Fax: 39-0577-318690
Section 513 Device Classification	807.87 (C) Class I	807.87 (C) Class I	807.87 (C) Class I	807.87 (C) Class I
Product code	JTW	JTW	JSM	JTW
Panel	Microbiology	Microbiology	Microbiology	Microbiology
Reason For Pre-market Notification	New device	New device	New device	New device

2 Predicate Device

	Coproset Salmonella	Coproset Shigella	Uriset preservative tubes	Swab set General use
Predicate Device Name	BD Difco™ Selenite Broth	BD Difco™ GN Broth, Hajna	BD Vacutainer™ PLUS Plastic Urine C & S preservative Tubes and Kits	BD Bacto™ Eugon Broth
Predicate Device 510(k)	K781304	K781304	K024240	K781304
Product Code	JSN	JSN	JSM	JSN
Predicate Device Company	BD Diagnostic System	BD Diagnostic System	BD Diagnostic System	BD Diagnostic System

3 SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE

3.1 Device Description

Coproset

disposable *in vitro* diagnostic device for the collection and transportation of stool samples and the enrichment of pathogenic organisms present in the sample.

Coproset Salmonella: In vitro Disposable diagnostic device with Selenite Broth intended for the collection and transport, from the collection site to the testing laboratory, of stool samples and for the enrichment of *Salmonella* spp.

Coproset Shigella: In vitro Disposable diagnostic device with GN Broth intended for the collection and transport from the collection site to the testing laboratory of stool samples and for the enrichment of *Shigella* spp.

Uriset Preservative tubes with holder

Disposable in vitro diagnostic device for the collection and transport of urine samples from the collection site to the testing laboratory.

Swab set General use

Disposable in vitro diagnostic device with Eugon Broth, intended for the collection and transport of pathogenic agents collected by swabs from the collection site to the testing laboratory and for enrichment of *Streptococcus pyogenes*, *Staphylococcus aureus*, *Candida* spp., *Streptococcus agalactiae*.

3.2 Synopsis of Test methods

Coproset

COPROSET has been designed for the collection and transport of stool samples and enrichment of the enteric pathogen which may be present.

Stool samples are collected with the spoon and maintained in liquid medium in optimal conditions during transport. The same container is used for enrichment of the pathogen to be detected, , after subsequent streaking on agar plates and appropriated incubation.

Uriset Preservative tubes with holder

URISSET is a calibrated vacuum-filled tube designed for the collection and transportation of urine samples for the detection of pathogenic agents.

Using the tube with the holder, the urine sample can be collected in conditions of safety for the operator and for the sample itself.

The tube fills with about 4 ml of urine and the preservative stabilizes the bacterial load.

Swab set General use

SWAB SET has been designed for the collection and transportation of samples collected on bacteriological swabs, and enrichment of the pathogen which may be present. Samples are collected using the swab accessory and maintained in liquid medium in optimal conditions during transportation.

3.3 Substantial Equivalence

As reported in M40-P NCCLS a Transport System is a device that ensures the integrity of the specimen and allows for a safe handling during the interval between specimen collection and processing the specimen in the laboratory. It consists of the liquid or semiliquid transport medium, the container of the transport system and in some cases, also sampling device.

Transport medium: Liquid or semisolid medium designed to preserve and maintain the integrity of the specimen for the time period between specimen collection and laboratory processing of the sample.

Following this definition and considering that Diesse Coproset and Swabset devices and their respective predicate devices have similar Intended use, indication for use, similar features and that the media are the same, we can consider DIESSE Device Substantially equivalent to their respective predicate device.

Performance evaluation, further demonstrate the substantial equivalence and the safety and effectiveness of Diesse Devices when compared with the respective Predicate Device: in the case of Coproset devices and Swab set device viability of pathogen is maintained and the results obtained are comparable with those obtained for predicate device;

Uriset preservative tubes with holder have the same intended use, Indication for use, material and design than its predicate device and thus it possible to conclude that they are substantially equivalent.

The results obtained in the comparison between Uriset preservative tube and Vacutainer demonstrate that DIESSE Uriset give a good performance in terms of sample preservation and data are comparable with those obtained for the predicate device.

Signature _____

Date: _____

Dr. Francesco Cocola
Director of Quality Unit/ Regulatory Affairs
Director, Research and Development

Indications for Use

510(k) Number (if known):

Device Name:

Coproset Salmonella,
Coproset Shigella,
Uriset preservative tubes,
Swab set General Use

Indications For Use:

Coproset Salmonella

In vitro Disposable diagnostic device with Selenite Broth intended for the collection and transport, from the collection site to the testing laboratory, of stool samples and for the enrichment of Salmonella spp.

Coproset Shigella

In vitro Disposable diagnostic device with GN Broth intended for the collection and transport from the collection site to the testing laboratory of stool samples and for the enrichment of Shigella spp

Uriset preservative tubes

Disposable in vitro diagnostic device for the collection and transport of urine samples from the collection site to the testing laboratory.

Swab set General Use


Disposable in vitro diagnostic device with Eugon Broth, intended for the collection and transport of pathogenic agents collected by swabs from the collection site to the testing laboratory and for enrichment of Streptococcus pyogenes, Staphylococcus aureus, Candida spp., Streptococcus agalactiae.

Prescription Use ☒ _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Division Sign-Off

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) KD70062



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Diesse Diagnostica Senese S.P.A.
c/o Casey Conroy
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
Melville, New York 11747

JUL 30 2007

Re: k070062

Trade/Device Name: Coproset Salmonella, Coproset Shigella, Uriset Preservative Tubes,
Swab Set General Use

Regulation Number: 21 CFR 866.2900

Regulation Name: Microbiological Specimen Collection and Transport Device

Regulatory Class: Class I

Product Code: LIO, JTW

Dated: July 16, 2007

Received: July 18, 2007

Dear Mr. Conroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

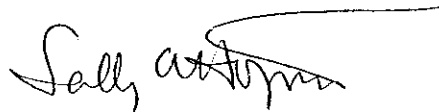
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sally A. Hojvat", with a long horizontal flourish extending to the right.

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Coproset Salmonella,

Coproset Shigella,

Uriset preservative tubes,

Swab set General Use

Indications For Use:

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In vitro Disposable diagnostic device with GN Broth intended for the collection and transport from the collection site to the testing laboratory of stool samples and for the enrichment of Shigella spp

Uriset preservative tubes

Disposable in vitro diagnostic device for the collection and transport of urine samples from the collection site to the testing laboratory.

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Prescription Use ☒ _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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NEEDED)

Freddie H. Peck Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) KD70062